REMARKS

The Office Action was stated to pertain to claims 2-18, however, claim 9 has been cancelled and therefore only claims 2-8 and 10-`8 are pending in the application.

Independent claim 17 and 18 were rejected under 35 U.S.C. §112, second paragraph as being indefinite because of the use of the word "improved" therein, which the Examiner stated is a relative term and the specification does not provide a standard for ascertaining the requisite degree of improvement encompassed within the scope of claims 17 and 18.

Independent claim 17 and claims 2-8 and 9-16 depending therefrom also were rejected under §112, second paragraph because the Examiner stated certain of those claims contained limitations that the Examiner considered to be method steps, which the Examiner stated were not appropriate for an apparatus claim.

In response to the latter rejection, certain of the claims have been editorially amended in an effort to provide structure or components that performs a stated function. As explicitly stated in MPEP §2173.05(g), there is nothing inherently wrong with defining some part of an invention in functional terms. Functional language, does not, in and of itself, render a claim improper. As further stated in MPEP §2173.05(g), a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.

Applicants submit that the functional language that remains in the claims has been tied to structure or components that perform that function, and therefore the

requirements MPEP §2173.05(g), and thus the requirements of 35 U.S.C. §112, second paragraph, are satisfied.

As to the use of the word "improved" in claims 17 and 18, those claims have been amended consistent with the discussion of "hidden" markers in the present specification at page 9, second paragraph. As described in that portion of the specification, and as now set forth in independent claims 17 and 18, the method and apparatus of the present invention allow efficient use to be made of markers that have not been previously approved, documented or proven to have a correlation to a specific medical condition. Nevertheless, these markers are still noted in the method and apparatus, as a result of the testing of the multiple biomolecular markers in the samples. When follow-up data are obtained from patient records, the method and apparatus check whether there is a correlation between different medical conditions in the follow-up data and the previously tested biomolecular markers that were previously not known to have a correlation to a particular medical condition. The present inventors have had the insight to recognize that by testing all of the multiple markers in a sample, and recording all test results even for markers that do not have a currently known correlation, if and when patient records indicate a different medical condition, a check can be made as to whether any of the previously-tested markers have the capability of predicting that condition, but were not, at the time, known or approved as correlators for that particular medical condition.

Applicants submit that this not only overcomes the rejection under §112, second paragraph, but also overcomes the rejections based on the prior art. Claim 17 was rejected under 35 U.S.C. §102(e) as being anticipated by Kleinschmidt et al.

Claims 2-7, 9-15, 17 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barnhill et al. in view of Wright, Jr.

None of these references discloses or suggests modification of an expert rule for use in identifying or diagnosing a medical condition, making use of "hidden" markers of the type described above. In all of these references, the markers that are used are the generally accepted, proven markers for a particular pathology or medical condition, and they are used in the conventional manner, even in the context of an expert system (neural network).

None of these references discloses or suggests keeping track of additional markers, in a multi-marker sample, and making use of those markers with regard to follow-up information obtained from the same patient, in order to determine whether any of the additional markers, with the hindsight provided by the follow-up information, is a reliable correlator to a particular medical condition, as set forth in independent claims 17 and 18.

The Kleinschmidt et al. reference, therefor, does not disclose all of the elements of claim 17 as arranged and operating in the claim, and thus does not anticipate claim 17.

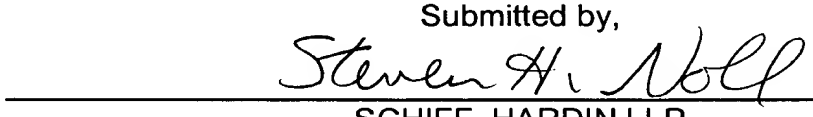
The combination of the teachings of Barnhill et al. and Wright, Jr. is not comparable to the subject matter of independent claim 17 or independent claim 18, and therefore neither of those claims would not have been obvious to a person of ordinary skill in the relevant technology based on the teachings of Barnhill et al. and Wright, Jr. Claims 2-7 and 10-15 (claim 9 having been cancelled) depend from claim 17, and would not have been obvious to a person of ordinary skill in the relevant

technology based on the teachings of Barnhill et al. and Wright, Jr. for the same reasons discussed above in connection with claim 17.

Claims 8 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Barnhill et al. and Wright, Jr., further in view of Kulikowski et al. Since those claims both depend from claim 17, the above arguments concerning the combination of Barnhill et al. and Wright, Jr. are applicable to this rejection as well. Even if the Examiner's statements regarding the teachings of the Kulikowski et al. reference are correct, modifying the Barnhill et al./Wright, Jr. combination in accordance with those teachings still would not result in a combination as set forth in claims 8 and 16, in view of their dependency from claim 17.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,



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